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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,231	02/01/2000	Jeffrey A. Hubbell	50154/002002	5903
21559	7590	07/09/2009		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER KOSAR, AARON J	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 07/09/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[patentadministrator@clarkelbing.com](mailto:patentadministrator@clarkelbing.com)

### Office Action Summary

**Application No.**

09/496,231

**Applicant(s)**

HUBBELL ET AL.

**Examiner**

AARON J. KOSAR

**Art Unit**

1651

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-13,15-19 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-13,15-19 and 51-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-883)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's arguments filed March 27, 2009 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

The claims are as presented September 23, 2008. Claims 1, 2, 4-13, 15-19, and 51-56 have been examined on the merits. Upon further consideration the indication of allowable subject matter is herein withdrawn in favor of the new grounds of rejection below. Any inconvenience to Applicant is regretted. Accordingly, since new grounds of rejection are presented this action is NON-FINAL.

### ***Terminal Disclaimer***

The terminal disclaimer to U.S. Patent No. 7,291,673 filed 9/23/2008 and the terminal disclaimers to U.S. Patent Nos. 6,958,212 and 7,413,739 filed 3/27/2009 have been reviewed and accepted. Accordingly the terminal disclaimers have been recorded.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-13, 15-19, and 51-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re *Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991 ), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See M.P.E.P. § 2163.02. In this case, the skilled artisan would not have reasonably concluded at the time of the invention that applicant was in possession of the entire invention as claimed.

Furthermore, the MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163.

In the instant case, the genera of “biomaterial” and of “precursor component” compounds embraced by the claims are limitless to any biomaterial or precursor component, and the limited number of species in the instant disclosure do not provide support for description of the entire genus. Accordingly, the skilled artisan would not have reasonably concluded at the time of filing that applicants possessed the genus of all “biomolecules” or all “precursor components” thereof.

It is noted that the claims in no way limit the scope of the structure of the biomaterial. Claim 1 refers to “a biomaterial” and “precursor components” but as discussed in the section 112, second paragraph, rejections below, these terms are not limited to any particular biomaterial and only claim 54 limits the precursor component compounds. The terms encompass any and all precursor component compounds and any biomolecules that share any structural or functional similarity to any compound capable of reacting by nucleophilic addition or to any biomolecule. The specification clearly and explicitly indicates that a biomaterial is limitless to any material and only recites an intended use (“which is intended for contact with the body, either upon the surface of it or implanted within it.” (page 8, paragraph 2). The biomaterial is thus described solely in functional language, and the specification provides no guidance (other than the few species therein and by implied trial-and-error) for determining which “biomaterials” or “precursor components” are useful for the method and which are not. In this case also, DNA is embraced by the genus of biomolecules, but it clearly does not include any acrylate or thiol

groups and Applicant has not provided any guidance for producing DNA with the claimed method; this level of disclosure is insufficient.

All other claims depend directly or indirectly from claim 1 and are, therefore, also rejected for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Von Seggern (8/20/1998, CA 2,281,602; IDS).

Von Seggern teaches a process contacting a polyvinylamine component (that is, a polyfunctional nucleophilic polymer) with a bis(meth)acrylate or bis(meth)acrylamide component (that is, a component having conjugated unsaturated groups/bonds)(page 19, lines 14-27). Von Seggern further teaches that the components polymerize by Michael addition reactions (that is, by nucleophilic addition) (page 19, line 25).

Claims 1, 2, 4, 6, 7, 9-12, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Ranucci (1991, Macromolecules, 24 (16), pages 4554-4558; Reference U).

Ranucci teaches a process comprising a “Michael-type polyaddition” polymerization (that is, a nucleophilic addition) of a bis(thiol) compound (that is, a precursor component having at least two strong “SH” nucleophiles) with a bis(acrylamide) compound (that is, a precursor component having at least two conjugated unsaturated bonds/groups, “C=C-C=O” (see page 4554, formula V), which are neither maleimide nor vinyl sulfone). The product of the reaction (for example, page 4554, right column, compounds of formulas VI through IX) also does not comprise albumin. Ranucci teaches that compound (for example formula V) is a peptide (that is, it contains a C(O)NH linkage) and is an oligomer or polymer (that is, it contains multiple bonds connecting distinct atoms or groups, including the poly(acrylamide) of bis(acrylamide)). Ranucci also teaches cross-linking the composition and forming a gel and washing with water (that is, the biomaterial is a hydrogel; page 4558, paragraph 7).

Although Ranucci does not explicitly teach a specific peptide sequence or reaction by which the composition or components function as binding/adhesion sites, because the claims are not limited to any peptide sequence or any binding/adhesion interaction and also because the instant process may comprise a limitless number of additional steps, then the process and components of Ranucci (e.g. the peptide linkage of the bis(acrylate) added in the number/quantity to perform the polymerization) are still deemed in some way to embrace the instantly claimed adhesion/binding site(s).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 2, 4-7, 9-12, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ranucci (1991, *Macromolecules*, 24 (16), pages 4554–4558; Reference U) in view of Trumbo (1993, *Polymer Bulletin*, 31, pages 523-529; reference V).

Ranucci teaches polymerizing by a nucleophilic addition reaction (“Michael-type polyaddition”, page 4554, paragraph 2) between strong nucleophiles (bis(thiol)) and conjugated unsaturated groups (bis(acrylamide).

Ranucci does not explicitly teach adding at least two amines or the reaction between.

Trumbo teaches that acrylates and acrylamides undergo Michael addition reactions with “a variety of electron rich species.” (page 523, paragraph 2) and that electron rich species (“B:”) comprise amine (-NH<sub>2</sub>), thiol (-SH), and hydroxy (-OH) compounds (page 523, scheme (1)).

The selection of an amine would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that bis(thiols) and polyamines (“poly(amidoamines)”) are polymerizing/polyaddition agents (Ranucci page 4554, paragraphs 2-3) and recognizing that in art of polymeric addition reactions, that amines, thiols, and “a variety of electron rich species” undergo the same bond-forming addition reactions (Trumbo, page 523, paragraph 2; page 527, paragraph 2). A holding of obviousness over the cited claims is therefore clearly required. See MPEP § 2144.06.



Claims 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ranucci and Trumbo as applied to claims 1, 2, 4-7, 9-12, and 51 above, and further in view of Aldrich (1996, Aldrich Catalog of Fine Chemicals, page 1211; reference W).

Ranucci and Trumbo are relied upon as above.

Ranucci does not teach a polyethylene glycol (PEG) precursor component(s).

Aldrich teaches that PEG and PEG diacrylate (CAS #[25322-68-3],[26570-48-9] respectively) were known and commercially available at the time of the instant invention (Aldrich, "Poly(ethylene glycol-400)" and "Poly(ethylene glycol-400) diacrylate", page 1211).

The selection of a PEG in the process of Ranucci would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that PEG is, a strong nucleophilic bis(hydroxy) compound (Aldrich, structural formula, page 1211); and recognizing from Trumbo that a variety of electron rich species, including hydroxy and thiol compounds, are equivalents in polyaddition/nucleophilic polymerization reactions (Trumbo, page 523, paragraph 2). A holding of obviousness over the cited claims is therefore clearly required. See MPEP § 2144.06.

Furthermore, the selection of a PEG diacrylate in the process of Ranucci would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that diacrylates (e.g. PEG diacrylate) and acrylamides, as taught by Trumbo (page 523, paragraph 2), are equivalent in that the diacrylates and diacrylamides undergo addition reactions in polyaddition/nucleophilic polymerization reactions. A holding of obviousness over the cited claims is therefore clearly required. See MPEP § 2144.06.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/  
Examiner, Art Unit 1651

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655